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## DIGITAL MINIMALLY INVASIVE SURGERY SYSTEM

### Background of the Invention

The present invention relates to the art of image guided surgery. It finds particular application in conjunction with neurosurgical and orthopedic procedures and will be described with particular reference thereto. However, it is to be appreciated that the present invention is equally applicable to a wide range of image guided surgical applications in humans as well as veterinary applications.

Heretofore, images of a region of a patient in which surgery is planned have been made using magnetic resonance imaging systems, computed tomography, or other similar imaging modalities. These techniques generate a substantial amount of data, which is then manipulated through software to provide three-dimensional guidance within the imaged region. Typically, to facilitate diagnoses and treatment through image guidance, this data is manipulated using a computer supplemented with other specialized computer hardware to display selected views during surgery, e.g., orthogonal views, slices, perspective renderings, or the like.

Acquired images used for image guided surgery typically use anatomical reference markers which are commonly imaged with the patient. At the surgical site, acoustic, infrared, video camera, or other tracking technologies are utilized to determine the location of the

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markers relative to the patient and the surgical site. Additional computer software is provided to register the coordinate system of the markers, hence the patient, with the image(s). Thereafter, the same system is used to

5 monitor the current position of surgical tools instrumented with similar markers, and coordinate their position in physical space with their position in the image(s). In this manner, the current position of the tool or probe relative to obscured portions of the

10 patient's anatomy is readily determined. This facilitates implementing minimally invasive techniques by allowing the surgeon to use the acquired image(s) to see below the visible surface of the patient. For example, the surgeon can use the software's graphic user interface to mark the

15 entry point and proposed trajectory of a pedicle screw on a patient's spine. The marked image(s) can then be used to enable the surgeon to follow the trajectory created below the surface with the instrumented surgical tool to be sure that the screw will not impinge the spinal cord

20 and that it will engage sufficient bone to anchor properly, and the like.

In prior image guided surgery systems, different tools have been used for different portions of the human anatomy. To accommodate the use of different tools, the

25 surgeon typically needs to calibrate the tool to the system. That is, the system needs to know the length, diameter, distances between various portions of the tool and the markers mounted on the tool, relative locations of markers and a tool axis, and the like. Prior image guided

30 surgery systems did not allow use of non-instrumented or standard surgical tools. Also, in prior image guided surgery systems, as new tools are developed or as tools are modified, information about the tools loaded into the system must be reloaded on the entire installed base.

35 Similar reinstallation problems occur when improvements are made to the software.

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Prior image guided surgery systems also relied on reusable surgical tools. This has several drawbacks. First, with use, tools with cutting edges become dull. Second, since the tools are sterilized between uses, infection to the patient is possible due to a potential failure of the sterilization procedure.

Typically, image guided surgery systems are universal, i.e., applicable to any portion of the human anatomy that can be clearly imaged with reference markers. Computer software is provided to handle the imaging and alignment needs in virtually any region of the human anatomy. In some instances, the image guided surgery software is incorporated directly into the diagnostic imaging device. In other instances, additional expensive hardware is provided separately.

Prior image guided surgery systems have also relied on a capital equipment sales model, which has resulted in limited market acceptance. Prior image guided surgery systems have been large in size and cost-prohibitive for most. The shipping logistics has been expensive and cumbersome.

The present invention contemplates a new and improved method for image guided surgery, which overcomes the above-referenced problems and several others.

#### Summary of the Invention

In accordance with one aspect of the present invention, a method of image guided surgery is provided which includes use of a (1) low cost integrated computer, (2) software-integrated disposable kits, (3) sterile disposable surgical tools and accessories, and a (4) tracking system used to locate the instrumented surgical tools during surgery.

In accordance with another aspect of the present invention, a low cost integrated computer is provided. The computer contains a portion of image guided surgery software to provide minimal user functionality

e.g., retrieval of previously saved surgical information, preoperative surgical planning, etc. Image guided surgery using this method is not possible with the computer alone. Full user functionality is enabled only when the proper digital medium obtained from a software-integrated disposable kit, as described below, is inserted into a drive on the computer. Standard peripherals e.g., keyboard, mouse, are also included with kit. A display is also provided but is not part of the kit. Wireless peripherals can also be included as part of the kit to enable remote access to the software's graphic user interface. The computer can be included as part of a low cost mobile cart as well.

In accordance with another aspect of the present invention, a software-integrated disposable kit is also provided which includes (1) sterile instrumented disposable surgical tools and (2) a disposable one-time use digital medium, which contains the remaining a portion of the image guided surgery software to enable full user functionality. The digital medium will contain at least (i) a one-time use application specific software module and (ii) descriptive information concerning the surgical tools and other accessories. Further, other accessories, such as cables used to connect the computer to an imaging device e.g., fluoroscope, in sterile condition in sterile packaging which are used in the identified surgical procedure are present in the kit. Other accessories, including but not limited to implants and other associated hardware may be included depending on the application.

In accordance with another aspect of the present invention, sterile instrumented disposable surgical tools are also provided. The tools are in sterile condition in sterile packaging and are used in the identified surgical procedure. The tools are instrumented with markers that can be visualized during an image guided surgery by a tracking system.

In accordance with another aspect of the present invention, an application specific software module is contained on the digital medium. The software module can only be used once and will function only when used in  
5 conjunction with the portion of the image guided surgery software that resides on the computer.

In accordance with another aspect of the present invention, acoustic, infrared, video camera, or other tracking systems are utilized to determine the location of  
10 the instrumented surgical tools. The tracking system can be used to track other accessories e.g., a registration phantom, as well. The tracking system can be incorporated into a separate mobile cart or integrated directly into the operating room infrastructure e.g., lights, ceiling.

At a surgical site, the digital medium is removed from the software-integrated disposable kit and inserted into the computer. The software which resides on the computer in conjunction with the software on the digital medium, processes electronic medical diagnostic  
15 images, registers the acquired images to the patient's anatomy, registers the acquired images to any other acquired imaging modalities e.g., fluoroscopy to CT, MRI. The location of the instrumented surgical tool(s) is tracked by simultaneously updating the tool's virtual  
20 representation in the image(s), or any combination or subset thereof, with movement of the tool(s) in physical space. After the surgery, the digital medium and the surgical tool(s) are disposed of as they are disposable and can only be used once.

One advantage of the present invention resides in low or no capital cost to hospital and medical facilities for the equipment.  
30

Another advantage of the present invention is that it enables automatic upgrade of the image guided surgery software and of the specifications, descriptions,  
35 and characteristics of the surgical tools residing on the computer upon insertion of the digital medium.

Yet another advantage of the present invention is the assured sterility of the surgical tools, accessories, and any other components of the system contained in the software-integrated disposable kit, which  
5 enter the sterile field.

Another advantage of the present invention is the assured sharpness and reliable maintenance of any other quality aspects of the surgical tools and guides.

Another advantage includes simplified patient  
10 billing.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

15 Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and  
20 are not to be construed as limiting the invention.

FIGURE 1 is a perspective view of a mobile cart in combination with a computer with peripherals including but not limited to a joystick, a display, accessories including but not limited to cables, and a tracking system  
25 in accordance with the present invention;

FIGURE 2 is a perspective view of a software-integrated disposable kit in accordance with the present invention; and,

FIGURE 3 is a diagrammatic illustration of a  
30 schematic for the computer in accordance with the present invention.

Detailed Description of the Preferred Embodiments

With reference to FIGURE 1, one embodiment of the invention mentioned herein includes a computer 10 that  
35 is mounted in a mobile cart 12 or other convenient

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location in a surgical suite outside of the sterile field. This may be on the wall or on a hospital cart that is not in use. In the illustrated embodiment, as the computer 10 is inserted into the cart, a series of electrical interconnections are made, including interconnection with a display e.g., a flat screen monitor 14, interconnection with an electrical wall outlet, backup power supply unit contained within the cart, or some combination thereof, interconnection with one or several tracking system cameras 16, and the like. The tracking system cameras 16 for tracking the location of markers including but not limited to acoustic sensors, infrared sensors, and the like, are mounted on mobile carts, suspended from the ceiling of the surgical suite, mounted in conjunction with other equipment in the surgical suite such as the lighting, the operating table, or the like. In one embodiment, the cart 12 includes a port for connecting the computer 10 with the central record storage system of the hospital via a network, a diagnostic imaging device 64, or other source of electronic images of the patient. In other embodiments, the computer 10 includes a disk, tape, or other media drive for receiving the image information via a portable medium.

With reference to FIGURE 2, for each surgical application, there is a corresponding software-integrated disposable kit 20. The kit 20 includes a sealed, e.g., shrink-wrapped, carry-case or unit 22 which contains all of the necessary equipment for performing a specific surgical procedure indicated on a label 24 on the outside of the kit. A variety of kits 20 are provided, each labeled for a specific surgical procedure or limited group of closely related surgical procedures. Each kit 20 typically includes the appropriate surgical tools for the corresponding procedure, such as instrumented drill guides 26, 28, instrumented probes 30, and other accessories as may be appropriate to the selected procedure. The tools are instrumented with markers 32 which are tracked by the

cameras 16, in the preferred embodiment. Additional markers 32 not attached to a tool may be included in the kit 20. In other embodiments, the markers 32 are acoustic or infrared transmitters whose signals are received by corresponding acoustic or infrared cameras 16. By tracking the markers 32 with one or several cameras 16, the current location of each marker 32, hence the associated tool, is readily determined by well-known triangulation techniques. In other embodiments, more than two cameras 16 or other sensors are provided for improved tracking even when the surgeon temporarily blocks access to one of the markers 32. Each of the drill guides 26, 28, probes 30, and other surgical tools and accessories are presterilized and wrapped in peel-open or other sterile packaging.

The kit 20 further includes several other components which are commonly used during image guided surgery. These components can include a universal tool tracker 34 which is mounted directly to a fixed location on the tool. The universal tool tracker 34 is used to track standard surgical tools that are not included as part of the kit 20. A registration phantom 36 that is attached to the operating room table or directly to the imaging device is also included and is used to register an acquired image(s) to the patient's anatomy. Depending on the surgical procedure, other components may be included such as a head frame 38 with markers for attachment to the patient. All the components contained in the kit 20 are again presterilized and prepackaged in sterile packaging.

The kit 20 further includes, but is not limited to, a user input device(s) 40 such as a joystick, mouse or keyboard with which the operator controls the software's graphic user interface. The user input device(s) 40 and their associated cable(s) are sterile and packaged in sterile packaging. During set-up for the procedure, the sterile packaging is opened and the cable(s) for the user input device(s) 40 is plugged into a corresponding port on



the computer 10 or mobile cart 12. Another embodiment includes a wireless user input device(s) that is recognized by the system, through an infrared port for example on the computer 10 or mobile cart 12.

5           The kit 20 can further include implants 42 and other surgical accessories that are used in the selected surgical procedure. For example, the kit 20 can include pedicle screws 42, rods 44, and mounting clamps 46, and the like as are appropriate for a surgical procedure on  
10 the spine. Different surgical procedures will, of course, have different surgical accessories in the kit 20. The surgical accessories are sterile and sealed in sterile packaging.

          The kit 20 further includes a one-time-use  
15 digital medium 50, such as a small high-capacity diskette, CD-ROM, DVD, or the like. The digital medium 50 is configured to be received into a drive 52 in the computer 10. The diskette 50 contains a portion of the software to be used during a surgical procedure, image processing  
20 algorithms specific to the application, dimensions and other specifications of the surgical tools and accessories in the kit 20, and other information of use during the surgical procedure.

          With reference to FIGURE 3, the computer 10 may  
25 include triangulation or tracking software and base or low-level graphics and other processing software 60. A video-grabber card or other similar input/output device for capturing still-images or live video includes an input/output port and/or interface 62 for receiving  
30 electronic images directly from an imaging device 64. Images can also be received through the computer network port by accessing central record keeping via the hospital's network. Optionally, the computer 10 may include a drive for reading the electronic image  
35 information obtained from the imaging device 64 from disk, tape, or other similar media. The computer 10 also includes a graphics card or the like with a port and/or

FIG. 3

interface 66 for connecting to the display 14. Likewise, the computer 10 includes a port and/or interface 68 for interconnection with the user input device 40. The computer 10 may also contain a port, an infrared port for example, for wireless connection to the user input device(s). The computer 10 further includes a port and/or interface assembly 70, which interfaces the tracking system's cameras 16 with the tracking software.

The one-time-use digital medium 50, in the preferred embodiment is a mini-diskette, which includes information useful for a specific surgical application. The medium contains an area for high-level graphics processing software 72 with the most recently revised algorithms for the graphics processes which are specific to the selected surgical procedure. The disks for different surgical procedures may have different high-level graphics processing software and information. The high-level graphics processing software 72 interacts with the low-level graphic processing software 60 to enable the computer 10 to perform the image and graphics processing which it may be called upon to perform during the selected surgical procedure. Various other electronic keys, including media such as CD-ROM and DVD for example, for enabling the computer 10 for image guided surgery are also contemplated.

The digital medium 50 further includes an area 74 for software which describes tool specifications. That is, software to describe the specifications of each of the tools, probes, guides, and any other necessary accessories in the kit. In conjunction with the tool(s) physical specifications, markers 32, and the tracking system's cameras 16, the image guided surgery software recognizes the tool and correlates its position, trajectory, end point, and any other necessary characteristics in physical space with it's virtual representation on the display 14.

The digital medium 50 further includes an area 76 for 3D virtual representations, images, or information,

in VRML format for example, of the instrumented tools contained in the kits. These files are used to create 3D virtual representations of each of the surgical tools. The 3D representations of the tools are superimposed on each acquired and registered image. These representations can be in wireframe or fully rendered format, for example, depending on the surgeon's preference. The 3D surgical tool information or image area 76 is accessed by the software on the computer and the digital medium and manipulated so the tools virtual representation in the image(s) is correlated to its 3D position in physical space as determined by the camera(s) 16.

The digital medium 50 further includes an area 78 for software that describes other information such as instructions with guides concerning common steps taken during the surgical procedure. For example, this section may include software information concerning the depth and diameter of the holes to be tapped for the surgical screws in the kit. It may include information or guidelines for the use or placement of the accessories in the kit, images from a previous or similar procedure, anatomy atlas tables containing information on certain anatomical angles and distances specific to an application, and the like. This portion of the digital medium 50 may also include software for upgrading the low-level graphics processing software 60 to the latest released revision.

The invention further includes a means 80 to ensure one-time-use of the digital medium 50. This means preferably resides in the computer 10. In one embodiment, this means erases all or part of the digital medium at the end of the procedure. Alternately, the software is encrypted to block reuse. In another embodiment, the digital medium 50 is physically deformed to prevent reuse. After the procedure, the tools and the digital medium 50 are disposed. Alternatively, the tool and the medium 50 are returned to the company for inspection, remanufacture, cleaning, sterilization, and/or repackaging.

In a preferred marketing procedure, the computer 10 is of limited cost. The computer 10 is sold to the hospitals at nominal or no cost. The cost of the computer 10 is recovered by the sale of the single use kits 20, the price of which is gauged to cover the cost of maintaining the computer 10 as well as the tools and accessories. This business model eliminates the traditional capital equipment sale process for conventional image guided surgery equipment. It also facilitates patient billing.

The invention has been described with reference to the preferred embodiment. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.